Measurement Technology Laboratory Gravimetric Analysis Technical Systems Audit Checklist
LOCATION: Research Triangle Park, North Carolina

Interviewer: James D. Noel	**Review Date:** 8/16/2019 + 8/26/2019 + 8/30/2019		
Scientist/Interviewee(s): Measurement Technology Laboratory	**Organization**	**Division**	**Branch**
Project(s) Title (if applicable): Measurement Technology Laboratory Gravimetric Analysis			
Laboratory/Locations Description (note room # in checklist for issues): Technical System Audit and Audit of Data Quality of Measurement Technology Laboratory Gravimetric Analysis.			

Questions for the Technical Systems Audit based on Project QAPP/SOP and ORD PPMs 13.2 and 13.4

	QUESTION	Y	N	N/A	COMMENT(S)
SECTION A. PROJECT SPECIFIC REQUIREMENTS					
4-100 PWS Vanderpool_FINAL.docx					
A1.	Is the weighing chamber (RTP E485-3) operating at 22° C and 35% relative humidity? (p. 3)	**Y**			Can confirm on 8-16-19 that the weighing chamber is operating per specification. There is historic temperature data that also shows operating temperature is under specifications.
A2.	Were requirements stated in ORD Policies and Procedures Manual 13.2, Scientific Recordkeeping: Paper, for maintaining research notebooks shall used? (NOTE: See Section B below) (p. 4)				Details are found in Section B
SOP: GRAVIMETRIC ANALYSIS OF TEFLON FILTERS USING AN AUTOMATED WEIGHING SYSTEM (Mega PE Gravimetric Analysis SOP 20180627.docx)					
A3.	Is the 24-hour mean of the temperature is between 20.0° C and 23.0° C before analysis has begun? (Both weighing chamber and environmental equipment) (p. 10)	**Y**			According to the weighing chamber log the temperature for the days in question are all within 20-23 C. (See Attachments for more information). Note: there is a difference in the RH and Temp logged and what is measured outside the weighing chamber door. (See Attachment).
A4.	Is the 24-hour mean of the relative humidity (RH) is between 30% and 40% before analysis has begun? (Both weighing chamber and environmental equipment) (p. 10)				Was not able to determine this information without access to RH logs.

Questions for the Technical Systems Audit based on Project QAPP/SOP and ORD PPMs 13.2 and 13.4					
	QUESTION	**Y**	**N**	**N/A**	**COMMENT(S)**
A5.	Is the difference between environmental conditions within the weighing chamber and the environmental equipment within 2.1 C and 2.1% RH of each other> (p. 13)				Was not able to determine this information without access to RH logs.
A6.	Do the filters have identification numbers (ID) printed on the them? Are the numbers from the same lot and sequential? (p. 14)				Was not able to determine this information without access to RH logs.
A7.	Are the filter numbers written in the project laboratory notebook? (p. 14)	**Y**	**N**		Filter numbers are recorded in research notebook but runs from 12/2018 are not recorded in the research notebook.
A8.	Do the petri dish holders have the same ID number as the filter> (p. 14)	**Y**	**N**		This was observed in the lab but was not easily understood through documentation in the research notebook.
A9.	Are the filters left open to the clean room to equilibrate for 24 hours before weighing? (p. 15)				This information is not readily found in the research notebook. However, evidence suggests that filters are left ot equilibrate by setting a delay on the analysis (See Attached)
A10.	Are three repetitions recorded for each weight? (p. 18)		**N**		Tare Weights Postship Tab in "20190516_KD_Master_RawData_Fall2018Round RobinSpreadsheet.xlsx" has 62 samples with NULL reading for third repetition. Only duplicate readings were taken for those samples.
A11.	Is an internal balance calibration performed with each run? (p. 18)				Was not able to determine this information without access to project notebook.
A12.	Is a working standard run every 10 filters? (p. 18)				See Comments below
A13.	Is a laboratory blank run every 10 filters? (p. 18)				See Comments below
A14.	Are all recorded gravimetric data stored electronically in the SQL databases associated with the automated weighing system PC? (p. 22)				Was not able to determine this information without access to SQL Database.
A15.	Is the filter equilibration time at least 24 hours? (p. 23)				Was not able to determine this information definitively without access to project notebook. However, evidence suggests that filters are left ot equilibrate by setting a delay on the analysis (See Attached)

Questions for the Technical Systems Audit based on Project QAPP/SOP and ORD PPMs 13.2 and 13.4				
QUESTION	**Y**	**N**	**N/A**	**COMMENT(S)**
A16. Is the filter equilibration temperature range 24 hour mean between 20.0-23.0° C? (p. 23)	**Y**			According to the weighing chamber log the temperature for the days in question are all within 20-23 C. (See Attachments for more information). Note: there is a difference in the RH and Temp logged and what is measured outside the weighing chamber door. (See Attachment).
A17. Is the filter equilibration temperature control < 2.1° C over a 24 hour period? (p. 23)	**Y**			According to the weighing chamber log the temperature for the days in question are all within 20-23 C. (See Attachments for more information). Note: there is a difference in the RH and Temp logged and what is measured outside the weighing chamber door. (See Attachment).
A18. Is the filter equilibration relative humidity control < 5.1% RH per hour? (p. 23)				Was not able to determine this information without access to RH logs.
A19. Is the Filter pre/post sampling RH difference in the 24 hour means < 5.1% RH? (p. 23)				Was not able to determine this information without access to RH logs.
A20. Is the Microbalance auto-calibration run Prior to each weighing session? (p. 23)				This information is not documented in the research notebook, but cannot confirm that the autocalibration is not done.
A21. Are three Exposure Lot Blanks run per lot? (p. 24)		**N**		Three Exposure Blanks are not run per session as noted in "20190516_KD_Master_RawData_Fall2018RoundRobinSpreadsheet.xlsx" for Tare Weights Preship, Tare Weights Postship, Loaded Weights Preship.
A22. Are the Exposure Lot Blanks < ±15.1 µg change between weighings? (p. 24)	**Y**			All weighings repetitions were < ±15.1 µg between weighings as seen in "20190516_KD_Master_RawData_Fall2018RoundRobinSpreadsheet.xlsx"
A23. Are Lab Filter Blanks run one every 10 filters or at least once per session? (p. 24)		**N**		Lab Filter Blanks are not run every 10 filters per session as noted in "20190516_KD_Master_RawData_Fall2018RoundRobinSpreadsheet.xlsx"

Questions for the Technical Systems Audit based on Project QAPP/SOP and ORD PPMs 13.2 and 13.4				
QUESTION	**Y**	**N**	**N/A**	**COMMENT(S)**
A24. Are Lab Filter Blanks < ±15.1 µg change between weighings? (p. 24)	**Y**			All weighings repetitions were < ±15.1 µg between weighings as seen in "20190516_KD_Master_RawData_Fall2018RoundRobinSpreadsheet.xlsx"
A25. Are Balance Check (working standards) run at the beginning, 10th sample, and end of every run and are within < ±3.1 µg from certified value? (p. 24)		**N**		Balance checks are run every 10 samples, but there are several failures (> 3.1 µg) throughout "20190516_KD_Master_RawData_Fall2018RoundRobinSpreadsheet.xlsx" in all tabs. A total of 57 workings standard checks failed when compared to the Weight Set Evaluation Report for 3A3611 and 75UX dated 9/25/2018.
A26. Do routine filter re-weighings (duplicate) occur once per session and are < ±15.1 µg change between weighings? (p. 24)		**N**		No filter re-weighings (other than Blanks, QC Standard Checks) are run per session as noted in "20190516_KD_Master_RawData_Fall2018RoundRobinSpreadsheet.xlsx"
A27. Does a Microbalance audit occur annually and are within < ±0.003 mg or manufacturers specs, whichever is tighter? (p. 24)				Was not able to determine this information, was not found in research notebook.
A28. Do Lab temperature logger check occur every 90 days within < ±2.1° C? (p. 24)	**Y**			A Log temperature logger logs the temperature in weighing room every day and there is indirect evidence that this occurs (See Attachments).
A29. Do Lab humidity logger check occur every 90 days within < ±2.1% RH? (p. 24)				Was not able to determine this information without access to RH logs.
A30. Do Microbalance calibration occur annually? (p. 24)				Was not able to determine this information, was not found in research notebook.
A31. Does Lab temperature certification occur annually within < ±2.1° C? (p. 24)				Was not able to determine this information, was not found in research notebook.
A32. Does Lab humidity certification occur annually within < ±2.1% RH? (p. 24)				Was not able to determine this information, was not found in research notebook.
A33. Do Working mass standards certification occur annually and within a 0.025 mg tolerance (ASTM Class 2)? (p. 24)	**Y**			In general, yes working standard certification does occur annually based on 2019 and 2018 certificates. However, from May 23, 2019 to June 4, 2019 the annual certification was out as the previous year

Questions for the Technical Systems Audit based on Project QAPP/SOP and ORD PPMs 13.2 and 13.4				
QUESTION	**Y**	**N**	**N/A**	**COMMENT(S)**
				certification ended on May 23 and the next year certification was not completed until june 4.
A34. Are Working mass standards compared to primary standards every 90 days and within a 0.025 mg tolerance (ASTM Class 2)? (p. 24)				Was not able to determine this information was not found in research notebook.
A35. Does Primary mass standards certification occur annually and within a 0.025 mg tolerance (ASTM Class 2)? (p. 24)				Was not able to determine this information was not found in research notebook.
SECTION B. ORD PPM 13.2 — PAPER RECORDS (PRINCIPAL INVESTIGATORS AND LABORATORY SCIENTISTS [if applicable])				
ORD PPM 13.2 - RESEARCH NOTEBOOKS				
B1. Does the researcher maintain an approved research notebook? Indicate the type in comments. Approved methods to document research activities currently consist of paper, ELN software, or the Microsoft OneNote application.	**Y**			Researcher has an approved notebook. See notes below.
B2. Do research notebooks contain a log of daily research activities, observations, and conclusions, and reference information (e.g. SOPs, computer file names, location, etc.) for project records/study files that are stored in other media (e.g., forms, instrument print-outs, computers)?		**N**		Researcher has evidence of maintaining a notebook however data found in "20190516_KD_Master_RawData_Fall2018RoundRobinSpreadsheet.xlsx" shows data analyzed in 12/2018 that is NOT found in the notebook. Also of note there are only 23 pages of notes for a year's worth of research.
B3. Are QA project plans and/or research work plan(s) cited in the notebooks? Are QAPPs maintained by the PI in the project record/study file?		**N**		QAPP is not cited in the Notebook.
B4. Do notebook entries include an explanation as to why that specific activity is being performed?		**N**		No there many notebook pages lack a research title on most pages.
B5. Are paper research notebooks bound, pre-numbered and of archival quality (supplied by NERL)? [N/A for electronic notebooks.]	**Y**			

Questions for the Technical Systems Audit based on Project QAPP/SOP and ORD PPMs 13.2 and 13.4				
QUESTION	**Y**	**N**	**N/A**	**COMMENT(S)**
B6. Does the cover of each notebook include the following information? - Project title - Name of notebook custodian(s) - Inclusive dates of research activities	**Y**			
B7. Is the following information provided in the front of each notebook? - Index cross-referencing all project notebooks and electronic files - Names and initials/signatures of project personnel - Table of Contents [N/A for electronic notebooks.] - List of error codes (if applicable)		**N**		There is no Table of Contents in research notebook. There is no evidence of electronic file locations cited in the notebook. Name, initials and date are missing on two pages (22 & 23).
B8. Are pages of the notebooks labeled with the following information? - Experiment/Research Activity Title - Project ID (only applicable if used for multiple projects) - Signature or initials of person recording data - Date (month, day, year) - Page number, [N/A for electronic notebooks.]		**N**		Research Activity Title is missing from several notebook pages. Signature and initials are missing on two page (22 & 23).

Questions for the Technical Systems Audit based on Project QAPP/SOP and ORD PPMs 13.2 and 13.4				
QUESTION	**Y**	**N**	**N/A**	**COMMENT(S)**
ORD PPM 13.2 – LOGBOOKS/SUPPORTING RESEARCH INFORMATION				
B9. Are records present for the following supporting research information (This may be captured in either logbooks, forms or research notebooks)? - Instrument use (date, user, samples, method) - Instrument/equipment maintenance - Calibration and/or calibration check (date, calibration standards used, person performing calibration or check, acceptability of results) if this information is not project specific and kept in the lab notebook - Standard preparation (date prepared, analyst, concentrations, procedures, expiration date) if this information is not project specific and kept in the lab notebook - Temperature monitoring (date, person making temp measurement, acceptability of measurement) - Standard materials (manufacturer, lot number, purity, concentration, expiration date)	**Y**			Calibration checks were found in the lab for weigh balances. Room temperature monitoring was seen via computer monitoring.
ORD PPM 13.2 - PRE-PRINTED FORMS AND INSTRUMENT PRINT-OUTS				
B10. Are pre-printed forms used to document routine data collection activities? If no, the rest of this section is N/A. Proceed to the next section				Not Observed
B11. Are three-ring binders used to compile data collected on pre-printed forms or instrument print-outs? If not, describe how these records are maintained.				Not Observed
B12. Are pages in three ring binders either consecutively numbered or labeled by section and consecutively numbered within the section?				Not Observed
B13. Is the following information clearly identified for each data set in a three-ring binder? - Project title - Data collector's name and/or initials				Not Observed

Questions for the Technical Systems Audit based on Project QAPP/SOP and ORD PPMs 13.2 and 13.4					
	QUESTION	**Y**	**N**	**N/A**	**COMMENT(S)**
	- Date of data collection				
B14.	Are pocket folders or similar methods being used to manage loose sheets of data?				Not Observed
ORD PPM 13.2 - MANAGEMENT OF PAPER LABORATORY RECORDS USING A PROJECT RECORD/STUDY FILE					
B15.	Are paper laboratory records dedicated to a specific project, research area, or laboratory activity to help ensure that research documentation be clearly identified, easily retrieved, and logically organized for storage?				Not Observed
B16.	Are clear and explicit supporting research information available for each project record/study file?				Not Observed
ORD PPM 13.2 - DOCUMENTATION REQUIREMENTS					
B17.	Are records maintained by multiple individuals signed (or initialed) and dated (including year, month, and day)? If records are maintained by a single individual, are records clear that only the individual is making the entries?				Not Observed
B18.	Is there any evidence that pages have been removed from the notebooks, logbooks, or binders?		**N**		
B19.	Are loose sheets affixed by a permanent method (e.g. clear archival quality tape or acid-free glue? [N/A for electronic notebooks.]	**Y**			
B20.	Is a line drawn across affixed material onto the notebook page, initialed and dated? [N/A for electronic notebooks.]	**Y**			
B21.	Is information and data recorded in the notebook as it is taken? Note any signs of post it notes, or other loose paper where information may be recorded.	**Y**			No evidence of post-it note use.
B22.	Are activities documented in chronological order (bound notebooks) or chronologically by section (three-ring binders)?	**Y**			
B23.	Are blank pages or unused portions of previous pages marked with a diagonal line? [N/A for electronic notebooks.]	**Y**			

Questions for the Technical Systems Audit based on Project QAPP/SOP and ORD PPMs 13.2 and 13.4				
QUESTION	**Y**	**N**	**N/A**	**COMMENT(S)**
B24. Are errors corrected with a single strike-through, initials, date, and brief reason or error code? If error codes are present, are codes listed in the front of the laboratory record or an applicable SOP referenced?		**N**		Improper strikethrough observed on pages 5, 20, 21
B25. Are abbreviations and acronyms clearly defined either in a table at the beginning of the record or reference to other documentation as to where they are defined (e.g. QAPP, SOP, etc.)		**N**		No abbreviation or acronym defined in table or SOP.
ORD PPM 13.2 - TRAINING ON LABORATORY RECORD DOCUMENTATION				
B26. Have PIs and project personnel received training on the requirements of this policy and procedure?				None Observed
B27. Has compliance with this policy been demonstrated within six months of the beginning of research activities for project personnel? If not, has additional training been provided on paper laboratory records documentation?				None Observed
ORD PPM 13.2 - REVIEW				
B28. Has the notebook been periodically reviewed by a supervisor or PI (e.g., Branch Chief at PARS) to ensure complete, accurate and legible documentation of research activities?		**N**		There is no supervisor sign off in the research notebook.
B29. Are notebook reviews documented such that a signature and date of the review is included on the last page reviewed?		**N**		
ORD PPM 13.2 - STORAGE AND DISPOSITION & ORD PPM 13.4 – DATA STORAGE				
B30. Are laboratory records retained and disposed of in accordance with EPA Records Schedule 1035 (formerly 501, 502, 503, and 507)?				Not considered.
OTHER DOCUMENTATION BEST PRACTICES				
B31. Are table, row, and column titles completely described in tables and any figures labeled as needed?		**N**		Some tables missing units for columns.
B32. Are data transformations/calculations and units of measure clearly documented?				

Questions for the Technical Systems Audit based on Project QAPP/SOP and ORD PPMs 13.2 and 13.4					
	QUESTION	**Y**	**N**	**N/A**	**COMMENT(S)**
B33.	Are QC checks and data verifications documented?		**N**		Not all QC checks in SOP are documented in the research notebook.
SECTION C. ORD PPM 13.4 MINIMUM QA/QC LABORATORY REQUIREMENTS					
C1.	Are research projects covered by approved QA Plans (e.g., QA Project Plan [QAPP], Research Plan [RP], or comparable document) that discusses quality issues? List documents verified and date of revision.	**Y**			
C2.	Are internal laboratory assessments performed on a schedule such that all laboratories are assessed at least once every 3 years using ORD PPM 13.4 as the assessment standard?		**N**		No evidence of audit or assessment observed.
ORD PPM 13.4 – STANDARD OPERATING PROCEDURES					
C3.	Are the PI's or his/her research support staff's routine work covered by approved standard operating procedures (SOPs)? Are SOPs periodically reviewed and readily available in the lab where the procedure is implemented?		**N**		Final signed off and approved SOP was not provided.
ORD PPM 13.4 - EQUIPMENT CALIBRATION & MAINTENANCE					
C4.	Is maintenance/calibration information documented in instrument logbooks or research notebooks and include identification of the equipment/instrument, user, date, activity performed, and results or observations?				Not Observed
C5.	Are analytical instruments maintained and calibrated on a regular basis (e.g. as specified in a manufacturer's instructions, QAPP, SOP, protocol, etc.)?				Not Observed
C6.	Are instrument logbooks kept with the instrument?				Not Observed
C7.	Is calibration documentation available for centrally managed equipment (e.g. balances, pipettors)?				Not Observed
C8.	**Major/Minor Analytical Instrumentation:** Are calibrations or calibration checks performed on major/minor analytical instruments prior to use with standards of known and documented uncertainty, traceable to recognized standard organizations, if applicable?				Not Observed

Questions for the Technical Systems Audit based on Project QAPP/SOP and ORD PPMs 13.2 and 13.4					
	QUESTION	**Y**	**N**	**N/A**	**COMMENT(S)**
C9.	**Major Analytical Instrumentation:** Are initial calibrations verified using a standard from a different (second) source (e.g., Standard Reference Materials (SRMs), Certified Reference Materials (CRMs), performance evaluation samples, or another standard from a different vendor) other than the one used for initial calibration? If a second source standard check is not being performed, is the justification documented? *Note: Use of SRMs or CRMs is strongly encouraged to provide for additional validation of the analytical process.*				Not Observed
C10.	**Major/Minor Analytical Instrumentation:** Are calibrations checked at the beginning and end of a sample set and periodically during use according to manufacturer's instructions or as otherwise documented based on QA category of the project?				Not Observed
C11.	**Supporting Equipment:** Is the accuracy of supporting equipment documented (e.g., pipettors)?	**Y**			Pipette and balance calibration certifications found.
C12.	**Balance Maintenance and Calibration:** Are balances serviced and calibrations re-certified annually using traceable (to international or national standards such as NIST) weights that encompasses the range of use of the balance by an ISO 17025 accredited vendor?	**Y**			
C13.	**Balance Maintenance and Calibration:** Are balance calibrations checked periodically during use (e.g., recommendation is once each day the balance is in use unless justification for less frequent checking is documented in a QAPP/SOP/facility manual).	**Y**			
C14.	Are weights used for calibration checks verified on a regular basis against traceable weights?	**Y**			
C15.	Are traceable weights calibrated at least once every 5 years by an ISO 17025 accredited organization?	**Y**			
C16.	**Environmental Conditions:** For conditions (e.g., temperature, pressure, humidity, atmospheric composition, or any other environmental condition) that are critical during the	**Y**			

Questions for the Technical Systems Audit based on Project QAPP/SOP and ORD PPMs 13.2 and 13.4					
	QUESTION	**Y**	**N**	**N/A**	**COMMENT(S)**
	implementation of analytical procedures (e.g., incubator temperature for microbiological tests), are those conditions monitored and documented to ensure the required range of the environmental condition is maintained?				
ORD PPM 13.4 – DEMONSTRATION OF ANALYST PROFICIENCY					
C17.	Prior to performing sample analysis with a method for which proficiency has not been previously demonstrated and documented, the analyst must demonstrate proficiency with the method by completing the following: (1) perform valid initial calibrations, (2) perform method detection limit determination, (3) demonstrate that they can meet all minimum QA/QC acceptance criteria as presented in the method document (e.g., SOP), and (4) if available, satisfactorily analyze a performance evaluation sample or a second source standard. Documentation of these activities shall be maintained by the Supervisor or their designee. Has this been done for all analysts?		**N**		No Demonstration of proficiency was found or observed.
ORD PPM 13.4 – SAMPLE STORAGE					
C18.	Are the temperatures for refrigerators/refrigerated rooms/freezers used to store samples monitored?	**Y**			
C19.	Is the minimum frequency of temperature monitoring and acceptance criteria defined and documented for each project or organization as needed?	**Y**			
C20.	Are samples stored and maintained to ensure their integrity as defined by applicable SOPs/QAPPs? For example, are samples stored away from standards, foreign/heavily-contaminated samples, or other materials, are the samples refrigerated or frozen at specified temperatures as needed, and are samples immediately returned to the refrigerator if it isn't consumed during an analytical procedure until it's determined that additional analyses are not needed?	**Y**			
C21.	Are samples analyzed/used within sample holding time/expiration dates to minimize the loss of analytes of interest as documented in	**Y**			

Questions for the Technical Systems Audit based on Project QAPP/SOP and ORD PPMs 13.2 and 13.4				
QUESTION	**Y**	**N**	**N/A**	**COMMENT(S)**
project-specific QAPPs/SOPs?				
ORD PPM 13.4 – STANDARD PREPARATION				
C22. Are stock standards and prepared reagents properly identified/recorded with the following: - Date prepared - Analyst identification - Identity of the stock/intermediate standard used including its source (e.g., manufacturer, lot number/identifier, etc.) - Identifying chemical information - Preparation procedures - Concentrations - Solvent, carrier or buffer - Applicable expiration dates?			**N/A**	
C23. Are the standards, chemicals, prepared reagents stored to maintain their integrity?			**N/A**	
ORD PPM 13.4 – QA/QC CHECKS				
C24. Are QA/QC checks of analytical procedures/methods/techniques being performed (e.g., use of spikes, blanks, standard curve in beginning/middle/end of analytical runs to check for instrument drift) as defined by applicable SOPs/QAPPs/facility manuals? *Briefly describe QC checks performed in Comments section.*		**N**		No see QC failures outlined in Section A.
C25. If QA/QC checks are not defined in an SOP/QAPP/facility manual, at a minimum, are positive controls (e.g., standards of known composition, matrix spikes), negative controls (e.g., blanks), and replicates (e.g., duplicates) performed periodically to demonstrate the accuracy and precision of a method for each unique matrix?				See QC failures outlined in Section A

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QUESTION	**Y**	**N**	**N/A**	**COMMENT(S)**
ORD PPM 13.4 – METHOD DETECTION LIMITS				
C26. Is the method for determination of the method detection limits (MDLs) or quantitation limits documented, if applicable? Are MDLs determined when results below the lowest calibration standard are reported?				Not observed.
ORD PPM 13.4 – DATA REVIEW				
C27. **Compliance with Acceptable Criteria:** Does the analyst review results for QC checks performed to determine compliance with acceptance criteria specified in the applicable SOPs/QAPPs/facility manuals? If acceptance criteria are not met, does the analyst perform corrective action as required by the applicable SOPs/QAPPs/facility manuals?	**Y**	**N**		Some QC is documented other failures are not. See Section A for specific Project QC failures.
C28. **Secondary Technical Review:** When required by a QAPP or when part of an assessment, has a representative sample of data that has been used or incorporated into a research product (journal article, report, etc.) been reviewed by a second technical person? If problems are identified, was an additional review performed to determine the extent of the problem? Have all data reviews been documented?				No secondary review is performed or outlined in QAPP.
OTHER MINIMUM QA/QC BEST PRACTICES				
C29. Are calibration records clearly linked to sample analysis?		**N**		Calibration standards are not found in data set nor are the results found in notebook.
C30. Are the treatment and use of QC data as noted in C24 clearly documented? If yes, briefly describe.		**N**		No see QC failures outlined in Section A.
C31. Is water being used of the proper quality (e.g., RNase and DNase free for molecular work, Type II for chemistry work, etc.)? Are			**N/A**	

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	QUESTION	**Y**	**N**	**N/A**	**COMMENT(S)**
	water systems maintained as per manufacturer's instructions (cartridges changed yearly, etc.)?				
C32.	Are results that fall outside calibration ranges qualified to reflect the fact that the accuracy of the reported concentration is uncertain? Is the concentration of the lowest calibration standard provided with those results so that a user of the data has as much information as possible about any concentration outside the instrument calibration range?			**N/A**	
C33.	For molecular or microbiology research, is proper work flow maintained?			**N/A**	
C34.	Are benches decontaminated as needed?			**N/A**	
C35.	Are labs generally clean and well maintained?			**N/A**	

COMMENTS

There are several QC failures noted in the dataset "20190516_KD_Master_RawData_Fall2018RoundRobinSpreadsheet.xlsx" that are not commented on within the research notebook (#4075). There seems to be a lack of supervisory oversight with no supervisor sign off and review of research notebook as well as no final signed approved SOP. There is also evidence of lack of training with no Demonstration of Proficiency/Competence documented. There seems to be the lack of recording of daily laboratory activities with the lack of entries (23 pages within one year). Each entry lacks obvious purpose, observations, and conclusions or next steps in each activity. Each activity does not record the laboratory conditions at the time of run including filter equilibrium times. The recording of these conditions seem to be important to the project as they are outlined in the SOP and should be recorded. Finally there is evidence that not all laboratory activities are being recorded in the laboratory notebook as there are runs (12/2018 in particular) found in datasets that are not recorded in the research notebook.

Data issues were also found. When comparing the data found in "20190516_KD_Master_RawData_Fall2018RoundRobinSpreadsheet.xlsx" (which correspond to the tare weights recorded in the research notebook) to "Round_Robin_Fall2018_EPAvsLabs Weights 20190313.xlsx" there seemed to be a systematic difference in approximately 15 µg in the tare weights in the "Tare Weights Preship" Tab to those recorded in the "preship exposed comp" tab. The tare weights found in the "preship exposed comp" tab do not seem to correspond to any recorded weight in the research notebook or the excel dataset. The differences are not obviously documented and may require further investigation.

PDF copy of the Research Notebook (#4075), the data compared of the original data as seen in unedited Excel Spreadsheet, as well as QC Check Excel spreadsheets by the reviewer are attached for convivence.

Reviewer(s) Completing Assessment Checklist	
Name/Title: James D. Noel / Quality Assurance Manager ORD/NERL/CED/IO	**Date:** 8/30/2019
Signature:  James D. Noel Digitally signed by James D. Noel Date: 2019.08.30 15:43:50 -04'00'	